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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,328

04/13/2004

Mark A. Roehrig

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

03/16/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/823,328	<b>Applicant(s)</b> ROEHRIG ET AL.	
	<b>Examiner</b> Snigdha Maewall	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-11 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,10,11,13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### Summary

1. Receipt of Applicants arguments and amended claims filed on 11/19/09 is acknowledged.

Claim 1 has been amended. Claims 5-9 and 15-20 remain withdrawn. Claims 2, 4 and 12 have been cancelled.

Claims **1, 3, 10-11 and 13-14** are under prosecution.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 10-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilgaard et al. (US PG pub. 20050019383) in view of Shaw et al. (USP 6231939).

Pilgaard et al. teaches patches for dermal and transdermal drug delivery (abstract). The reference teaches barrier layer separating the active ingredient from the adhesive. The barrier layer may be in the form of a polymer or a metal layer impermeable to the active ingredient and to the adhesive layer (see page 1, paragraph

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[0004]). The article has adhesive layer which adheres to skin, which has a first component constituting a continuous layer and at least a second component which is located in indentations in the adhesive surface of the first component and the second component is separated by barrier layer (see paragraph [0016], page 1). The second component may act as reservoir. (See paragraph [0022]). The barrier layer may be arranged in a pattern over the dressing in order to distribute the active ingredient in a desired way (see paragraph [0048] on page 3). The barrier layer comprises a metal foil which could be aluminum or a laminate of one or more layers or plurality of barrier layers (see paragraphs [0025, 0026, 0028 and 0048] on pages 2 and 3. The article comprises a backing layer which may be polyurethane film or foam or combination of film layers (see paragraph [0051]), (instant specification exemplifies polyurethane as one of the components constituting the backing layer, see page 8 second paragraph). (reads on backing film substrate), (thus the backing film will be translucent since the prior art and the instant disclosure both disclose backing film material to be polyurethane). The flange which is a continuation of barrier layer is taught to be of an average thickness of less than about 0.045 mm (see page 1, paragraph [0016]). Therefore, regarding the claimed size of the barrier layer, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan absent evidence of any unexpected results associated with the claimed thickness.

Although the reference discloses the barrier layer as constituting metal foil, it does not specifically disclose barrier layers with aluminum oxide or other metal oxides as claimed in instant claim 1.

Shaw et al. disclose deposition of barrier films for inhibiting penetration by oxygen or other gases employing a cross-linked acrylate layer and a layer of oxygen barrier material see column, 1 line 14-17. The reference further teaches that a transparent barrier film may be formed on a polyethylene, polypropylene, polyester or nylon substrate, or other thermoplastic substrate. First, a layer of acrylate monomer is deposited on the substrate and cross linked. The acrylate layer is then coated with an oxygen barrier layer of silicon oxide and aluminum oxide, both of which have good resistance to oxygen permeability. The high temperature resistance of the cross linked acrylate layer permits the notably higher temperature deposition of silicon oxide or aluminum oxide on the thermoplastic substrate see column, 3 lines 14-22.

.It would have been obvious to one of ordinary skill to have incorporated a barrier layer comprising aluminum oxide or silicon oxide in the teachings of primary reference in order to have good resistance to oxygen permeability motivated by the teachings of secondary reference.

Furthermore, it would have been obvious to one of ordinary skilled in the art to modify the application of barrier layer and make it substantially continuous since the prior art by Pilgaard teaches that the barrier layer may be arranged in a pattern over the dressing in order to distribute the active ingredient in a desired way and Shaw teaches barrier films comprising aluminium oxide which provides resistance to oxygen

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permeability. Substitution of one known film with another to provide predictable results would have been obvious to one of ordinary skill in the art to obtain predictable results. Since the material used in barrier layer of Shaw is same as the claimed barrier layer, the property of the layer being translucent would not be excluded because property of a compound cannot be separated from the chemistry of the compound.

Based on the teachings of the prior art , it would have been obvious to one of ordinary skilled in the art at the time of the instant invention to prepare a transdermal drug delivery device comprising reservoir, a barrier layer and backing layer with a reasonable expectation of success.

### ***Response to Arguments***

4. Applicant's arguments filed 11/19/09 have been fully considered but they are not persuasive.

Applicants argue that the barrier in Pilgaard et al. is internal to the carrier layer and serves to separate the reservoir and adhesive. Hence there is no motivation in Pilgaard et al. for that barrier to be translucent as required by Claim 1. In fact, the only metal barrier specifically disclosed in Pilgard et al. are "metal foils, such as aluminum" which would be expected to be opaque. Translucency in the inorganic barrier layer in Applicants' invention is important for cosmetic purposes, not a consideration relevant to the function of the barrier in Pilgard et al. Applicant further argues that Shaw does not pertain to transdermal devices and the barrier film of Shaw has unrelated function, hence Shaw does not cure deficiencies of Pilgard, the rejection shall be withdrawn.

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These arguments are not persuasive because Pilgaard has not been relied for the translucent barrier layer rather Gale's reference has been relied for substituting the barrier layer made of aluminium oxide which provides the translucent properties to the device. Since Pilgaard teaches utilization of metallic barrier layers, substitution of one known barrier layer with another known barrier layer made of aluminium oxide which provides better properties such as resistance to oxygen permeability would have been obvious to produce predictable results. Since the prior art by Gale teaches translucent property of such barrier layer, no unexpected results have been shown by the applicants. As discussed in the rejection above, the translucent property of barrier layer is associated with the aluminium oxide barrier layer of the prior art, that is Gale's reference. Therefore, the translucent behavior of barrier layer would flow naturally since the property of a compound cannot be separated from the chemical constitution of the compound. Additionally motivation to combine the prior arts elements need not be same as applicant's motivation. In the instant case gale provides the teachings that such barrier layers provide good resistance to oxygen permeability, thus one of ordinary would have utilized better barrier layer providing good resistance to oxygen and thus enhancing stability of the transdermal device. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicant's arguments that Shaw does not pertain to transdermal device and has unrelated function, it is

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respectfully pointed out that instant specification discloses that inorganic barrier layers comprising metal oxides are prepared by utilizing Shaw's methods disclosed in (USP 5,725,909, 5,440,446 and 6,231,939) on page 9, lines 1-10 and 23-30. The rejections will be maintained.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612